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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,199	06/23/2001	David O'Leary	NHC0031A-USA	8435
530	7590	10/16/2007	EXAMINER	
LERNER, DAVID, LITTBENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			PATEL, NIHIR B	
		ART UNIT	PAPER NUMBER	
		3772		
		MAIL DATE	DELIVERY MODE	
		10/16/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/888,199	O'LEARY, DAVID	
	<b>Examiner</b>	<b>Art Unit</b>	
	Nihir Patel	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on July 23<sup>rd</sup>, 2007.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2 and 16 is/are rejected.
- 7) Claim(s) 3-15 and 17 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed on July 23<sup>rd</sup>, 2007 have been fully considered but they are not persuasive. First the applicant argues that Schaeffer does not disclose the recess receiving medicament "when aligned with the dispensing port". The examiner disagrees. Column 5 lines 10-20 of the Schaeffer clearly states that "In operation, the user initially rotates the dosing member to the position in which the dosing recess is directly below the aperture 11, and thus in communication with the reservoir 6", indicating that the recess does receive medicament "when aligned with the dispensing port".

The applicant also fails to show how the aperture 11 functions as a pressure relief port and further fails to indicate where Schaeffer discloses first and second sealing surfaces. Again, the examiner disagrees. When "the user rotates the dosing member 3 through 180 degrees to bring the recess into alignment with the aperture at the radially inner end of the outlet" is defined as the first sealing surface. When "the user initially rotates the dosing member to the position in which the dosing recess is directly below the aperture and thus in communication with the reservoir" is defined as the second sealing surface. The pressure relief port is defined as sealed when the dosing recess is directly below the aperture because the aperture 11 has a pharmaceutical grade rubber sealing ring or washer incorporated in a groove around the aperture 11 to prevent ingress of moisture between the body and dosing member inherently indicating that 11 is also a pressure relief port. The pressure relief port is unsealed when the user rotates the dosing member 180 degrees to bring the recess into alignment with the aperture at the radially inner end of the outlet".

The applicant also argues that Schaeffer does not teach or suggest “a linear channel communicating with the dispensing port”. The examiner disagrees. When the dosing member is aligned with the aperture a linear channel is formed that communicates with the dispensing port.

The applicant also argues that Schaeffer does not teach or suggest “a cup assembly movably received in the channel”. Again, the examiner disagrees. The examiner defines the statement “movably received in the channel” as the dosing member being rotated (movably) until it is aligned with the aperture to form a linear channel (received in the channel).

Finally the applicant argues that Schaeffer does not teach or suggest “a sealing spring biasing the first sealing surface against the reservoir”. The examiner disagrees. The spring 25 is biasing the first sealing surface against the reservoir as defined by the definition the examiner provided in the above paragraphs.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Schaeffer et al. (US 6,065,471).

4. As to claim 1, Schaeffer teaches an apparatus that comprises a sealed reservoir 6 (see figure 4 and column 3 lines 15-20) including a dispensing port 8 (see figures 1, 2, and 4; column 3 lines 60-67); a channel 11a (the extended downwardly wall from the base is

**defined as the channel)** communicating with the dispensing port and including a pressure relief port **11**(see figures **1, 11 and 12; column 4 lines 5-15**); a conduit **12** (see column 4 lines **10-20**) providing fluid communication between an interior of the sealed reservoir **6** and the pressure relief port **11** of the channel **11a**; a cup assembly **3** movably received in the channel and including a recess **22** (see figure **7 and column 5 lines 10-20**) adapted to receive medicament from the reservoir when aligned with the dispensing port **8** (see column 5 lines **10-20**), a first sealing surface adapted to seal the dispensing port when the recess is not aligned with the dispensing port (see column 5 lines **30-35**), and a second sealing surface adapted to seal the pressure relief port when the recess is aligned with the dispensing port and to unseal the pressure relief port when the recess is not aligned with the dispensing port (see column 5 lines **30-35**).

5. **As to claim 2,** Schaeffer teaches an apparatus that includes the cup assembly **3** having a sealing spring **25** biasing the first sealing surface against the reservoir (see column 4 lines **40-50**).

6. **As to claim 16,** Schaeffer teaches an apparatus wherein the reservoir includes a volume of dry powdered medicament (see column 3 lines **25-45**).

*Allowable Subject Matter*

7. Claims **3-15 and 17** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach a reservoir that includes a collapsible bellows adapted to increase pressure within the interior of the reservoir upon being collapsed, when the pressure relief port is sealed. The prior art also does not teach a cup

assembly that includes a cup received in a cup sled movable within the channel, the cup defining the recess and the first sealing surface, and the sled defining the second sealing surface.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3772

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit 3772



Nihir Patel

  
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10/12/17